

REMARKS

The Office Action dated April 8, 2004, has been received and reviewed. Claims 1-13 and 16-63 are pending in this application. Claims 14-15 and 63-93 have been withdrawn from consideration by the Examiner due to a restriction requirement. Applicants have canceled these claims without prejudice or disclaimer. Claims 4-11, 20-25, 27-30, 34-42, 46-56 and 58-60 have also been canceled. Claims 94-107 have been added. Applicants respectfully request reconsideration of the application in view of the amendments above and remarks below.

Applicants wish to thank Examiner Kallis and Examiner Nelson for the opportunity to conduct a personal interview for this application on July 15, 2004, at which Applicant's representative, Jarett K. Abramson, and Eric S. Furman, via telephone, were present. The pending rejections and cited art were discussed and the present amendments and remarks are presented herein in response to those discussions.

I. Claim Objections

Claims 1, 7-9, 12, 16, 22-23, 26, 31-38, 40-41, 46, 48, and 57-58 have been objected to as allegedly containing various informalities. Applicants have subsequently amended or canceled these claims to comply with the objections raised in the Office Action. Accordingly, Applicants respectfully request that the objections to Claims 1, 7-9, 12, 16, 22-23, 26, 31-38, 40-41, 46, 48, and 57-58 be withdrawn.

II. Drawings

The drawings are objected to as purportedly containing copying artifacts. Applicants have included a copy of formal drawings with this response. Accordingly, Applicants respectfully request that the objection to the drawings be withdrawn.

III. Information Disclosure Statement

Applicants have included with this response a copy of all non-US patent references for the Information Disclosure Statement submitted September 24, 2001 as requested in the Office Action. Additionally, Applicants submit herewith a Supplemental Information Disclosure Statement to submit documents cited in the European Search Reports for the corresponding application numbers 04004192.3-

2405 and 04004191.5-2405. Each document listed on the Supplemental Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign not more than three months prior to the filing of the Supplemental Information Disclosure Statement submitted herewith. Accordingly, no fees are believed due in connection with the submission of the Supplemental Information Disclosure Statement.

Also submitted herewith is a copy of the Information Disclosure Statement previously filed on December 30, 2003 along with a copy of the PTO-1449 as filed in the parent application serial number 09/021,286 filed February 10, 1998. As discussed with the Examiner, a copy of each of the cited references will be provided for consideration by the Examiner.

IV. Claim Rejections – 35 U.S.C. § 112, first paragraph, written description

Claims 1-13 and 16-62 stand rejected under 35 U.S.C. § 112, first paragraph as allegedly failing to comply with the written description requirement. Applicants respectfully traverse this rejection. Applicants note that the United States Patent and Trademark Office carries the initial burden of establishing why a person skilled in the art would not recognize that the written description provides support for the claims, and that there is a strong presumption that an adequate written description of the claimed invention is present when the application is filed. 66 Fed. Reg. 1099 (January 5, 2001). Thus, the rejection of an application for lack of an adequate written description is meant to be a rare occurrence. 66 Fed. Reg. 1099 (January 5, 2001).

As discussed during the interview, Applicants have amended Claims 1-3, 12, 16-19, 26, 31-33, 43-45, 57, and 61-62 to claim fragments of a QTPase nucleic acid of SEQ ID NO 1 or a complement thereof or nucleic acids of greater than or equal to 30 consecutive nucleotides of SEQ ID NO. 1 that hybridize to a nucleic acid of SEQ. ID. No. 1 under specific conditions. Applicants note that the present application provides substantial support for these amendments in the canceled claims and throughout the specification (*see* U.S. Publication No. 2002/0108151A1). More specifically, paragraphs 38, 41, 80, 84, and 87 of U.S. Publication No. 2002/0108151A1 disclose fragments of a QTPase nucleic acid of sequence SEQ ID NO: 1. The examples in the specification, for instance, substantially support the

claimed fragments and provide significant utility. In Example 2, radiolabeled fragments of QTPase transcripts were hydrolyzed by alkaline hydrolysis to average lengths of 100 to 200 nucleotides and these fragments were used to perform the *in situ* hybridization that confirmed that the QTPase gene is found in the root cortex of the plant. In Example 3, the amount of QTPase mRNA in Nic1 and Nic2 tobacco mutants was ascertained using radiolabeled QTPase cDNA fragments. In Example 4, topped tobacco plants were analyzed for QTPase mRNA levels using radiolabeled QTPase cDNA fragments. Furthermore, Applicants note that the claimed fragments can be used in analysis following the approaches described in Examples 2, 3, and 4, to monitor the prevalence of the QPRTase transcript in successive generations of genetically modified tobacco. Monitoring the prevalence of the transcript in the genetically engineered tobacco is commercially important to insure that the reduced nicotine tobacco is in fact being grown in the planted fields rather than a tobacco that has reverted to wild-type, by for example, loss of the construct. Such a use or application of the claimed fragments is readily recognized by those of skill in the art. Accordingly, an abundance of written description support and a substantial utility for the claimed fragments is provided in the specification.

Additionally, Applicants note that the application in paragraph 45, discloses the value of probes for differential hybridization for screening tobacco libraries. Applicants also note that the hybridization conditions set forth in the claims are disclosed in the present application in paragraph 44.

Applicants note that the claims as amended are directed to a class of molecules defined by their sequence, i.e. hybrids greater than or equal to 30 nucleotides, and as such, as the sequence mismatch increases, the ability to hybridize decreases. As shown in the Applicants IDS references, Applicants have not found a nucleotide sequence at the time of filing that matches a 30 nucleotide sequence as claimed in the present invention. Accordingly, Applicants respectfully request that the 35 U.S.C. § 112, first paragraph rejection be withdrawn and that the application proceeds to issue.

V. Claim Rejections – 35 U.S.C. § 112, first paragraph, enablement

Claims 1-13 and 16-62 stand rejected under 35 U.S.C. § 112, first paragraph as allegedly not reasonably providing enablement. Applicants respectfully traverse this rejection.

Applicants note that the "test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation." (MPEP §2164.01, citing *In re Wands*, 858 F.2d 731, 737). Furthermore, the test for whether or not the enablement requirement has been met involves determining whether or not practice of the invention as claimed involves "undue experimentation". It has long been settled that "the key word is 'undue', not 'experimentation'". *In re Angstadt*, 190 USPQ 214, 219 (C.C.P.A. 1976).

For the presently claimed application, Applicants submit that the application of the current technology requires routine effort, and not undue experimentation. Applicants note that suppression has been used as a tool to identify gene function and that as such, a wide range of application from targets for therapeutics or pesticides and even therapy. See, Sharma et al., *Anticancer Res.* 1996 16(1) 61-9; Mann et al., *J. Clin Invest*, 2000 106(9) 1071-5. It has been demonstrated that in some plants and organisms, the production of double-stranded RNA provides a more efficient method of post-transcriptional suppression and that in the case of transgenic plants, a high percentage of transgenic lines have shown significant reduction of the target gene product and a reduced amount of activity. See, Waterhouse et al., 1998, *PNAS*, 95:13959-13964.

Given the present disclosure, one of skill in the art certainly understands how to make and use the claimed QTPase fragments. In fact, approaches to make and use the claimed fragments are provided in the specification. Applicants note that they disclose the manufacture and use of *in vitro* QTPase RNA fragments labeled with ³⁵S-ATP as a probe to detect QPTase RNA (see discussion of Example 2, *supra*), wherein an alkaline hydrolysis step was employed. Example 2 specifically illustrates examples of 100 and 200 nucleotide sequences that complement QPTase RNA. This example also notes conditions for a second version of hybridization. Examples 3 and 4 also describe the use of radiolabeled QTPase cDNA fragments.

Applicants note that the claims as amended meet the test of considering all of the Wands factors as a whole. Again, Applicants note that one of skill in the art could readily use probes as a monitor for the prevalence of the QPRTase transcript in successive generations of genetically modified tobacco. Accordingly, Applicants

submit that the present claims are enabled and respectfully request that the enablement rejections be withdrawn.

VI. Claims Rejections – 35 U.S.C. § 112, second paragraph

Claims 1-13, 16-25 and 27-56 have been rejected allegedly under 35 U.S.C. § 112, second paragraph, for various informalities, i.e. antecedent basis and the like. Applicants have amended the claims as suggested by the Examiner and respectfully request reconsideration and withdrawal of the rejections to Claims 1-13, 16-25 and 27-56

VII. Claims Rejections – 35 U.S.C. § 101

Claim 44 is rejected under 35 U.S.C. § 101 as allegedly the claim is directed to non-statutory subject matter. Applicants respectfully traverse this rejection for the reasons set forth below. Specifically, it is alleged that under Mendelian inheritance of genes, the seeds produced would be $\frac{1}{4}$ wild type. Applicants submit that the claim as amended recites a seed from a transgenic tobacco plant as recited in Claims 13, 31 or 43. These seeds would carry the transformed cells for transgenic tobacco plants and as such, the progeny would carry the transgene that distinguishes the presently claimed plants from the wild type. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection to Claim 44.

VIII. Claims Rejections – 35 U.S.C. § 102(b)

Claims 1-2 stand rejected under 35 U.S.C. § 102(b) as allegedly not being novel in view of Hughes et al. Case law holds and the M.P.E.P. states that a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Brothers v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Furthermore, the identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The cited art fails to disclose the subject matter contained in the claims of the present invention. Applicants submit that Hughes et al. does not disclose the nucleotide sequence of SEQ ID NO: 1, or the claimed fragments thereof. Accordingly,

In re: Conkling et al.
Application No. 09/963,340
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Applications respectfully request reconsideration and withdrawal of the rejections to
Claims 1-2.

CONCLUSION

In view of the remarks presented herein, Applicants respectfully submit that the claims define patentable subject matter. If, in the opinion of the Examiner, a telephonic conference would expedite the examination of this matter, the Examiner is invited to call the undersigned attorney, Jarett K. Abramson, at (919) 854-1400.

It is not believed that an extension of time and/or additional fee(s)-including fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. In the event, however, that an extension of time is necessary to allow consideration of this paper, such an extension is hereby petitioned under 37 C.F.R. §1.136(a). Any additional fees believed to be due in connection with this paper may be charged to our Deposit Account No. 50-0220.

Respectfully Submitted,



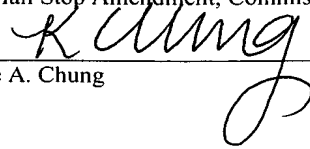
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Katie A. Chung



Attorney Docket No. 5051.338CT

PATENTS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

re: Conkling, et al. Confirmation No: 1188
Serial No.: 09/963,340 Group Art Unit: 1638
Filed: September 24, 2001 Examiner: Kallis
For: *REGULATION OF QUINOLATE PHOSPHORIBOSYL TRANSFERASE EXPRESSION*

Date: December 30, 2003

Commissioner for Patents
PO Box 1450
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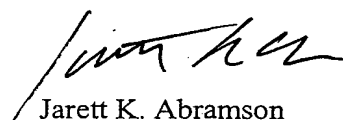
Attached is a copy of the PTO-1449 as filed in parent application serial number 09/021,286; filed February 10, 1998, with the application number and filing date of the parent application struck through and the application number and filing date of the above-referenced application written in.

A copy of each of the references above has been submitted to, or cited by, the Examiner in the parent application and is not provided herewith.

It is requested that all of these documents be considered by the Examiner and officially made of record in accordance with the provisions of 37 C.F.R. §1.56 and Section 609 of the MPEP.

No fee is believed due. However, the Commissioner is hereby authorized to charge any deficiency or credit any overpayment to Deposit Account No. 50-0220.

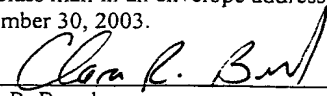
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Clara R. Beard

FORM PTO-1449

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.
5051-338C TAPPLICATION NO.
~~09/021,286~~ 09/463,340INFORMATION DISCLOSURE STATEMENT
BY APPLICANT

(USE SEVERAL SHEETS IF NECESSARY)

APPLICANT
Conkling et al.FILING DATE
~~10 February 1998~~ September 24, 2001GROUP
1638

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5051-338APPLICATION NO.
09/021,286INFORMATION DISCLOSURE STATEMENT
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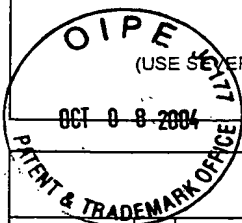
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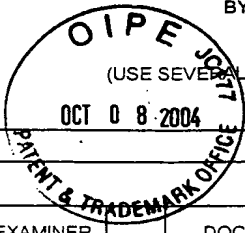
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| FORM PTO-1449 | U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE | ATTY. DOCKET NO. 5051-338 | APPLICATION NO. 09/021,286 |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (USE SEVERAL SHEETS IF NECESSARY)  | | APPLICANT Conkling et al. | |
| | | FILING DATE 10 February 1998 | GROUP 1638 |

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| EXAMINER INITIAL | | DOCUMENT NUMBER | DATE | COUNTRY | CLASS | SUBCLASS | TRANSLATION | |
| | | | | | | | YES | NO |
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| | 105 | WO 01/68836 A2 | 20.09.01 | Beach et al. | | | | |
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| | 112 | WO 93/17116 | 02.09.93 | Hooykaas et al. | | | | |
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| | 130 | WO 99/10512 | 04.03.99 | Dirks et al. | | | | |

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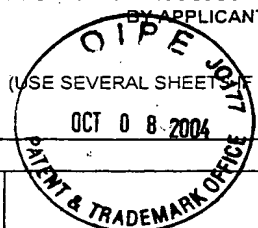
FOREIGN PATENT DOCUMENTS

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| | 132 | WO 99/25854 | 27.05.99 | Gordon-Kamm et al. | | | | |
| | 133 | WO 99/32619 | 01.07.99 | Fire et al. | | | | |
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| 174 | Genbank entry AC105416. Homo sapiens BAC clone RP11-310A13 from 4, 12-Jun-2002, 47 pp. |
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